

**Submission Applicant/Official Correspondent**

Kenneth J. Stanton, President  
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NOV 30 2006

Registration No. 2087418

Device Listing No. E408504

510(k) Number: K062688

Submitted: September 7, 2006

**A. Description of the Device**

**Trade Name:** Powder-Free Black Latex Examination Glove With Protein Labeling Claim

**Common Name:** Examination Gloves

**Classification Name:** Patient Examination Glove (per 21 CFR 880.6251)

**Class 1:** Powder-Free Latex examination glove 80LYY that meets all of the requirements of ASTM D3578-05.

**Predicative Devices:** Latex Powder-Free Examination Gloves

**Intended Use of the Device:** A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between the patient and the examiner.

SUMMARY PREMARKET 510(k) NOTIFICATION  
Powder-Free Black Latex Examination Glove  
With Protein Labeling Claim  
510(k) Number: K062688

**Summary of Technological Characteristics:****Material:** Latex      **Cuff:** Beaded**Powder Residue:** Maximum 2mg/glove**Quality Assurance:** In compliance with ASTM D3578-05, EN 455-1: 2000, EN 455-2: 2000, EN 455-3: 2000, ISO 2859-1:1999 and manufactured under ISO9001:2000**Inspection Parameters:**

<b><u>Criteria</u></b>	<b><u>Inspection Level</u></b>	<b><u>AQL</u></b>
Dimensions	S-2	4.0
Physical Properties	S-2	4.0
Water Tight Test 1000ml	G-1	1.5
Visual Major Defects	G-1	1.5
Visual Minor Defects	G-1	2.5

**Physical Properties:**

Dimensions:

Overall Length: 240 mm minimum

Width: 95 mm minimum (for medium glove)

Palm Thickness: 0.13 to 0.18mm (at center of palm)

Finger Thickness: 0.15 to 0.20 mm (at 15mm from tip of center finger)

Cuff Thickness: 0.10 to 0.15 mm (at 40mm from the beaded end)

	<b><u>BEFORE AGING</u></b>	<b><u>AFTER AGING</u></b>
Tensile Strength:	21.0. Mpa minimum	16.0 Mpa minimum
Ultimate Elongation:	700% minimum	500% minimum
Pinhole AQL	1.5 minimum	1.5 minimum

**Special Properties: Black Colorant****Packaging:** 100 pcs per dispenser box, 10 boxes per case, 1,000 gloves per case**Sizes:** XXS – XXL**Conclusion:** The Powder-Free Black Latex Examination Glove With Protein Labeling Claim meets the physical property requirements of ASTM D 3578-05, the FDA 1000 ml water test both before and after aging, and the Protein Labeling Claim Level at <50ug/g.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Kenneth J. Stanton  
President  
UG Healthcare (USA), Incorporated  
2420 Carson Street, Suite 125  
Torrance, California 90501-3163

NOV 30 2006

Re: K062688

Trade/Device Name: Powder-Free Black Latex Examination Glove with Protein  
Regulation Number: 880.6250  
Regulation Name: Patient Examination Glove  
Regulatory Class: II  
Product Code: LYY  
Dated: November 8, 2006  
Received: November 15, 2006

Dear Mr. Stanton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K062688

Device Name: Powder-Free Black Latex Examination Glove with Protein

Labeling Claim.

Indications for Use: The Powder-Free Black Examination Glove with Protein Labeling Claim (50 micrograms or less total water extractable protein per gram of glove), is a disposable device intended for Medical Purposes that is worn on the examiners hand to prevent contamination between patient and examiner.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

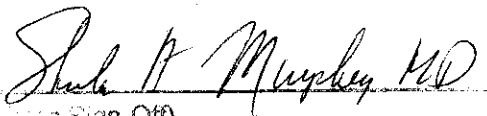
AND/OR

Over-The-Counter Use   X    
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Signature Sign-Off)  
Division of Anesthesiology, General Hospital,  
Division Control, Dental Devices

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